

NEBRASKA BOARD OF PHARMACY
MEETING MINUTES
March 6, 2006

ROLL CALL

Curt Barr, R.P. Chair, called the meeting of the Board of Pharmacy to order at 8:00 a.m. in the Staybridge Room of the Staybridge Suite, located at 2701 Fletcher Avenue, Lincoln, NE. Copies of the agenda were sent to Board members and other interested parties prior to the meeting. The following Board members answered roll call:

C. Curt Barr, R.P., Chairperson
Kevin Borchert, R.P., Vice-Chairperson
Linda Labenz, Secretary
Richard Zarek, R.P.

Absent: Roger Kaczmarek, R.P.

A quorum was present and the meeting convened.

Also present from the Department were: Becky Wisell, Section Administrator; Vonda Apking, Credentialing Coordinator; Cecilia Curtis-Beard, Credentialing Specialist; Pharmacy Inspectors: Tony Kopf, R.P., Ronald Klein, R.P., and Mike Swanda, R.P.; Duane Newland and Jeff Newman, Investigators, and Michael Grutsch, P.A., Program Manager, from Investigations Division; Sam Augustine, R.P., Board of Health; and Lisa Anderson, Assistant Attorney General.

REVIEW OF AGENDA

Additions, Modification, Reordering and Adoption of Agenda

Klein requested the Board to remove Item 10 - Pharmacy Technician Manuals from the consent agenda for further discussion. Barr requested the application of Larry Larson be removed from the consent agenda for further discussion. Labenz requested to discuss the FYI regarding the NABP Survey on Prescription Drug Repository Program under agenda Item 11. Labenz moved, seconded by Zarek, to approve the agenda as amended with the Chairperson having the authority to rearrange as needed. Voting aye: Barr, Borchert, Labenz, and Zarek. Absent: Kaczmarek. Voting nay: None. Motion carried

Adoption of Consent Agenda

Zarek moved, seconded by Labenz, to approve the consent agenda as amended. Voting aye: Barr, Borchert, Labenz, and Zarek. Absent: Kaczmarek. Voting nay: None. Motion carried

REPORT FROM THE DEANS

Dr. Clarence Ueda, Dean at University of Nebraska Medical Center (UNMC) College of Pharmacy, addressed the Board. Dr. Ueda reported on the following three areas: 1) Day-to-Day Functions; 2) Advanced College Agenda; and 3) ACPE Accreditation.

Dr. J. Chris Bradberry, Dean at Creighton University Medical Center School of Pharmacy and Health Professions, addressed the Board. Dr. Bradberry reported on the following two areas: 1) ACPE Accreditation and 2) Centennial Update.

Labenz asked if there were any faculty positions available. Dr. Bradberry stated that Creighton has two faculty positions available and are currently recruiting to fill those positions.

Barr thanked both Deans for updating the Board.

**INVESTIGATIONAL REPORTS , DISCIPLINARY AREPORTS AND CONTROLLED SUBSTANCES AUDIT REPORTS–
CLOSED SESSION**

Zarek moved, seconded by Labenz, to close the session at 8:45 a.m. to receive investigation reports, disciplinary reports and controlled substances audit reports. Voting aye: Barr, Borchert, Labenz, and Zarek. Absent: Kaczmarek. Voting nay: None. Motion carried

Labenz recused herself from the meeting at 8:59 a.m.
Labenz returned to the meeting at 9:09 a.m.
Barr recused himself from the meeting at 9:30 a.m.
Barr returned to the meeting at 9:43 a.m.
Barr recused himself from the meeting at 10:00 a.m.
Barr returned to the meeting at 10:01 a.m.

Zarek moved, seconded by Labenz, to reopen the session at 10:50 a.m. Voting aye: Barr, Borchert, Labenz, and Zarek. Absent: Kaczmarek. Voting nay: None. Motion carried

DISCIPLINARY/NON-DISCIPLINARY INFORMATION – ACTIONS TAKEN/PENDING –CONSENT – OPEN SESSION

(7) Disciplinary/Non-Disciplinary Information – Actions Taken/Pending – Consent

Disciplinary/Non-Disciplinary Information – Actions Taken/Pending

Name	Actions Taken and/or Pending	Alleged Violation
Bader, Tom	Denial of Initial Licensure Application Hearing 1/31/06 – Continued Hearing 3/16/06 – Continued Hearing 3/27/06	Answered “No” to having ever been disciplined, but documentation showed that he had been disciplined in Colorado.
Domeier, Dennis	Petition for Disciplinary Action 12/16/05 Order on Agreed Settlement 1/24/06 – <ul style="list-style-type: none">• 2 year Probation• Civil Penalty of \$2500	Defendant filled eleven prescriptions for hydrocodone-based medications for a local physician assistant’s immediate family members. None of the prescriptions were based on a medical emergency.
Niedbalski, Steven T.	Petition for Disciplinary Action and Temporary License Suspension 1/27/06 Hearing 2/8/06 Amended Petition for Disciplinary Action and Temporary Suspension 1/27/06 Order for Temporary License Suspension 1/27/06 License Suspended 1/27/06	Theft of controlled substances over a period of two years; failure to report termination of employment within 30 days; possession of a controlled substance; felony conviction.

Name	Actions Taken and/or Pending	Alleged Violation
Potmesil, Howard Shannon	Petition for Disciplinary Action and Temporary License Suspension 6/30/05 Order for Temporary License Suspension 7/1/05 Hearing 7/12/05 Order on Agreed Settlement 7/11/05 <ul style="list-style-type: none"> • 5 year Probation • Civil Penalty \$500 • Censure 	Misrepresentation of material facts in procuring a license; theft of pharmaceuticals from place of employment; possession of Ativan for own use without a prescription; admitted to hospital for manic-depression; reported to emergency room staff that he may do harm to himself and family.
Pranno, Faith Mary	Petition for Disciplinary Action 10/4/05 Hearing 1/27/06 Action pending	Dispensed a medical order for "Brookhouser Solution" compounded by a pharmacy technician. The solution dispensed was compounded using 176 mg of Atropine instead of .176 mg. Admitted that she was the pharmacist responsible for verifying the accuracy of the medical order.
Sysel, Stewart	Petition for Disciplinary Action 2/17/06 Hearing Action pending	Dispensed prescription to an infant for Zantac with directions to take ¾ tsp bid and it should have been take ¾ ml bid.
Turner, Fred A.	Petition to Revoke Probation 11/7/05 Hearing 12/21/05 Amended petition to Revoke Probation 12/6/05 Findings of Fact, Conclusions of Law and Order 2/16/06 Revocation 2/26/06	UA tested positive for ethanol; failure to provide proof of attendance at support group meetings; failure to submit monthly reports of the use of controlled substances.
Weaver, William	Petition for Disciplinary Action 1/23/06 Order on Agreed Settlement 2/16/06 <ul style="list-style-type: none"> • 2 year Probation • Civil Penalty \$3,000 	Defendant filled eleven prescriptions for hydrocodone-based medications for a local physician assistant's immediate family members, none of the prescriptions were based on a medical emergency; filled a prescription for a six-month old child for Pancof PD with directions to take 1-2 tsp every 4-6 hours but the prescriber ordered ¼ tsp every 6 hours. The directions for use prepared by the defendant are consistent with the amount prescribed for an adult.

Name	Actions Taken and/or Pending	Alleged Violation
Wells, James	Petition for Disciplinary Action 10/20/05 Hearing 12/20/05 continued Proposed Agreed Settlement 10/20/05 Order Rejecting Agreed Settlement 10/28/05 Hearing 2/22/06	Audit results showed significant losses of controlled substances; failure to keep accurate records of receipt and disposition of controlled substances.

Non-Disciplinary Information – Actions Taken/Pending

Name	Actions Taken and/or Pending	Alleged Violation
Birkel, Nicholas	Assurance of Compliance 2/15/06	Compounded and dispensed Domperidone outside the Investigational New Drug protocol defined in 21 USC §355(i) and 21 CFR 312.
Kicken, Joan	Petition for Disciplinary Action 9/15/05 Assurance of Compliance 2/4/06 Order to Dismiss the Petition 2/6/06	Dispensed prescription for Roxanal with directions to take 10ml by mouth every 3 to 4 hours as needed. The chart order provided for 10mg po every 3 to 4 hours prn.

(9A) – Pharmacist Intern Application with Misdemeanor/Felony Convictions (1) – Consent

(9B) – Pharmacist Applications with Disciplinary Action (2) – Consent

(9C) – Reinstatement of a Pharmacist License After Non-Disciplinary Revocation of More Than One Year (1) – Consent

(9D) – Mail Service Pharmacy Renewal (1) – Consent

APPROVAL OF MINUTES

January 24, 2006

Pages 1-4: No changes.

Page 5: Under Wholesale Drug Distribution Act, 2nd paragraph, delete the last sentence that states “Barr added that he received a letter from Martha Russell, Cardinal Health.”

Page 6-9: No changes.

Zarek moved, seconded by Labenz, to approve minutes from January 24, 2006 as amended. Voting aye: Barr, Borchert, Labenz, and Zarek. Absent: Kaczmarek. Voting nay: None. Motion carried

February 16, 2006 - Conference Call

Page 1: No changes.

Labenz moved, seconded by Zarek, to approve the conference call minutes from February 16, 2006. Voting aye: Barr, Borchert, Labenz, and Zarek. Absent: Kaczmarek. Voting nay: None. Motion carried

APPLICATION REVIEW

Labenz moved, seconded by Borchert, to approve the pharmacist application of Larry Larson. Voting aye: Barr, Borchert, Labenz, and Zarek. Absent: Kaczmarek. Voting nay: None. Motion carried

PHARMACY TECHNICIAN MANUALS (1)

Klein informed the Board that the Wal-Mart and Sam's Club technician manuals were not completed correctly and would be submitted to the Board at a later date.

Labenz moved, seconded by Zarek, to approve the technician manual submitted by Depot Drug. Voting aye: Barr, Borchert, Labenz, and Zarek. Absent: Kaczmarek. Voting nay: None. Motion carried

LEGISLATION UPDATE

Wholesale Drug Distribution Act (LB 318)

Wisell thanked all the Board of Pharmacy members and Kelly Boryca, Pfizer, for their involvement in developing and introducing LB 318. Wisell also thanked those members who attended the press conference for LB 318.

Karen Nishi, Cardinal Health, addressed the Board. Ms. Nishi asked the Board if there was a shortage, would there be a provision to expand the section of LB 318 so wholesalers could sell to other wholesalers without a pedigree.

Barr answered no. LB 318 was designed to address the sale of drugs from one wholesaler to another wholesaler for the purpose of stopping counterfeit drugs. If the Governor decided to declare a "state of emergency", then the Governor could suspend statutes at that time.

Zarek asked Ms. Nishi if it would be difficult for her company to obtain a pedigree. Ms. Nishi said she felt it was but if it was necessary for her company to obtain a pedigree, then they would. Ms. Nishi said she felt it would be expensive. In order for her company to have a pedigree, it would require them to have a paper trail or electronic trail. Barr stated he was informed through Healthcare Distribution Management Association (HDMA) that the transactions requiring a pedigree would be less than 0.05% of all transactions.

Ms. Nishi thanked the Board for their time and opportunity to speak to them.

Wisell suggested getting the original taskforce together to address regulations development. **Action Item: Wisell will request that the original members of the taskforce and set a meeting date to develop regulations.**

Ms. Boryca stated that the Iowa Board was holding their first meeting for their rules today and invited all the wholesalers, manufacturers, etc. Ms. Boryca stated that she would share information from Iowa with the Department. Ms. Boryca also stated, if LB 318 passed, electronic pedigree would not become effective until July 1, 2008. However, regulations would need to be effective no later than July 1, 2007.

Ms. Boryca questioned whether criminal background checks would be required. Wisell commented that the criminal background statutory language is very specific of which applicants are required to have criminal backgrounds checks.

Mr. Hospodka commented that the definition of manufacturing should exclude compounding.

Immunosuppressant Repository (LB 1079)

Wisell stated that LB 1079 has been designated a priority bill by the Speaker. Wisell stated the Department did not take a position on this bill but provided a technical letter pointing out the Department's concerns.

Borchert stated that he and Kaczmarek testified at the hearing and the Senators were not pleased with the Board's position on this bill. Mr. Augustine commented that the Board of Health supported the bill. Zarek commented that the bill would effect maybe one to two people in Nebraska a year.

Labenz stated that the completed NABP survey regarding drug repository programs showed that there were only two other States that had repository programs. Mr. Augustine stated that the Board of Health feels the bill would be beneficial and does not see the bill as a safety problem. **Action Item: Staff will forward a copy of the survey to the Board of Health.**

Labenz asked if the donated drugs were ever inspected for compliance with the regulations. Wisell said that participants voluntarily choose to participate in the program and they are required to inspect the drugs to determine if they are safe. Zarek commented that he would not be comfortable as a consumer receiving donated drugs to treat cancer.

Labenz discussed the NABP Survey of Prescription Drug Repository Program dated February 24, 2006. Ms. Anderson informed the Board on page 6 under Question 9 "Have there been problems with the donated drugs", under the State of Nebraska it reads:

"The original legislation was amended in 2005 to require the department to establish a registry of participants in the program. The Nebraska Board of Pharmacy has implemented these provisions, and the registry is available on their Web site at ..."

Ms. Anderson asked the Board if they were comfortable with that statement. Staff provided the statutes, regulations and the link to the web site to NABP. Labenz stated that the information on the survey was given to other states and the information is inaccurate. Barr stated that the Board did not recommend approval of the regulations. Mr. Augustine added even though the Board did not approve the regulations, the Board of Health approved them and the regulations were implemented by the Department. Wisell commented that the language could be corrected by stating that the Department implemented the approved regulations. **Action Item: Wisell stated she would contact NABP and seek a correction in what was stated on the survey.**

Wisell thanked both Borchert and Kaczmarek for testifying at the hearing on LB 1079 and stated she thought they did an excellent job.

Cancer Drug Repository Program (LB 1116)

Wisell informed the Board that this bill was advanced for engrossment on February 28th and correctly engrossed on March 1st. Wisell looks for this bill to pass.

Uniform Licensing Law Rewrite (LB 1177)

Wisell stated there was a hearing on February 10th.

Other Legislation

Wisell discussed the ULL rewrite with the Board. Wisell discussed briefly the proposed practice act changes and asked the Board if they had any additional changes. **Agenda Item: Practice Act changes for review.**

Wisell informed the Board that there was an informational meeting on March 23rd of the Credentialing Review Committee in which the credentialing review process will be discussed.

2007 LEGISLATIVE PROPOSALS

Registering Pharmacy Technicians

Wisell discussed who would introduce legislation concerning the registration of pharmacy technicians with Ron Briel. The Board should introduce the legislation since they were the applicant group. Zarek stated that he felt that pharmacy technicians should be added to the ULL. Wisell commented that there were several areas the Board would need to discuss before introducing legislation. Such areas would be fees, renewal, mandatory reporting, training within a certain time, pharmacist being responsible for making sure pharmacy technicians are registered, discipline and whether to include a grandfather clause for registering. Wisell commented that a grandfather clause would need to be in the introduced legislation in order to be permitted, but this type of language actually goes against the idea of uniformity of the ULL rewrite. **Action Item: Wisell will discuss the grandfather clause in the pharmacy technician registration legislation with Department Legal.**

Ms. Cover told the Board that the members of the NPA were opposed to the mandatory reporting law of pharmacy technicians. She added if the technicians are required to adhere to mandatory reporting, the reporting should be limited to only what technicians actually are allowed to do. Mr. Hospodka stated that he hoped technicians would be involved in this review process. Zarek stated that there were two pharmacy technicians involved as original stakeholders. Wisell stated that pharmacy technicians could address their concerns during the legislative hearing.

Borcher commented that the Board should be prepared to address the pharmacy intern exemption during the ULL rewrite legislation, noting Dr. Schaefer's position on mandatory reporting.

Wisell said she would contact the original stakeholders to set a meeting date to work on the legislative language for the Board to consider. She also said a concept paper would need to be submitted in June. The Board agreed that mandatory reporting for pharmacy technicians should be required. **Action Item: Wisell will schedule a meeting with the original stakeholders to develop the legislation for the 2007 Legislative session.**

PROPOSED AMENDMENTS TO 175 NAC 8 REGULATIONS GOVERNING PHARMACIES

The Board reviewed the proposed changes to 175 NAC 8 Regulations Governing Pharmacies. The Board decided that the definition of Long-term care facility should read as amended but add "intermediate care facility for the mentally retarded". The Board discussed 8-004.06 and determined that it should read "Change of Ownership or Premises: The licensee must notify the Department in writing 30 days before a pharmacy is sold, leased, discontinued, or moved to a new premises." The Board discussed 8-006.03A and determined that "computerized or electromagnetic record keeping" should be deleted and "electronic record keeping systems" be added in its place. The Board discussed 8-006.05C6 and determined not to add letter "f" and also delete letter "e" from this section.

Zarek stated that the Board could develop a template to use as a guideline for what pharmacies could do for disaster preparedness. Barr discussed that NABP is working on a Disaster Preparedness Plan. Ms. Cover stated that the NPA is currently working on developing a plan to assist pharmacies for different disasters. Borcher stated that hospitals are required to have a Disaster Preparedness Plan. Mr. Augustine informed the Board there are grants available at both Creighton and UNMC to assist in this process.

2007 LEGISLATIVE PROPOSALS CON'T

Automated Dispensing in Long-term Care (LTC) Facilities

There is a workgroup meeting in May.

Barr commented that the Board should revisit the pseudoephedrine bill because of changes in the federal law.

MEDICARE D

Barr stated that he heard that there has been a decrease of patient care due to the large amount of administrative time spent on processing the new Medicare D program. Barr added that his pharmacy has had a lower gross profit margin and cash flow due to the program. There are problems with dual eligible patients, contracts and pre-authorization that need to be addressed. Zarek stated he spoke with the dual eligible patients ahead of time and has not had a bad transition. He added there were 14 contracts available but he chose to sign only three of the contracts. Zarek stated that he has had a good experience.

PRESCRIPTION DRUG MONITORING PROGRAM (PMP) GRANT

Klein informed the Board of NAMSDL conference in April in Washington, D.C. Travel would be at the cost of the Board. The Board requested that Klein attend. **Action Item: Klein will gather information about the conference and staff will request travel authorization.**

LICENSEE ASSISTANCE PROGRAM (LAP)

Judi Leibrock, LAP Program Coordinator, provided an update to the Board. The Board thanked Ms. Leibrock for her update.

PATIENT SAFETY RFP UPDATE

Wisell informed the Board due to the amount of \$50,000, the Department of Administrative Services needs to complete an additional review before the RFP can be publicized. **Action Item: Staff will adjust the dates in the RFP.**

REQUEST FOR INFORMATION ON DRUG DESTRUCTION

The Board discussed a letter received from Rachael Herpel, Community Programs Director, for the Groundwater Foundation. The Board commented on the questions and directed staff to develop a letter of their responses. **Action Item: Staff will develop a letter of the Board's responses and forward to Barr for approval.**

ATTACK ON ASTHMA NEBRASKA UPDATE

Barr questioned why the data was so limited. **Action Item: Staff will request an explanation from Attack on Asthma as to why the data was so limited.**

JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATION SURVEY

No action taken.

ACCREDITATION COUNCIL FOR PHARMACY EDUCATION – APPROVAL OF PHARMACY PROGRAMS

Zarek moved, seconded by Labenz, to approve the list of ACPE accredited programs. Voting aye: Barr, Borchert, Labenz, and Zarek. Absent: Kaczmarek. Voting nay: None. Motion carried

NABP ISSUES

Barr said District V had two vacant positions available. The Board discussed the NABP Annual meeting scheduled in April. All the Board members and Kopf are scheduled to attend.

COMMITTEE REPORTS

MPJE Committee

Nothing to report at this time.

Tri-Partite Committee on Internship

Nothing to report at this time.

Formulary Advisory Committee

Wisell explained that two new members have been appointed to the committee. The new members are Brenda Kiolbasa, R.P. and Amy Renard, R.P.

FINANCIAL REPORT

The Board discussed that the budgeted amount for travel expenses should be increased. The Board would like to discuss buying laptops for paperless meetings. **Action Item: Wisell stated pharmacy should have enough funds available to buy laptops but she would look into this further.**

Zarek moved, seconded by Barr, to have an estimate on laptop computers for all the Board members at the next Board meeting. Voting aye: Barr, Borchert, Labenz, and Zarek. Kaczmarek was absent. Voting nay: None. Motion carried. **Agenda Item: Purchasing Laptops for Paperless Meetings.**

ACTION ITEMS

Apking informed the Board that she is waiting on an answer from Department Legal concerning the Board paying the cost of the PSAM examination for the professional Board members. Barr offered to write a newsletter article on mandatory reporting. **Action Item: Barr will write a newsletter article on mandatory reporting.**

Hospodka requested that the Board get written clarification from DEA regarding wasting or destroying a controlled substance. **Action Item: Wisell will obtain written clarification from DEA regarding wasting and destroying a controlled substance.**

CORRESPONDENCE AND GENERAL INFORMATION

The Board rescheduled their July meeting for July 27, 2006. **Action Item: Staff will book a conference room at the Embassy Suites for the July meeting.**

Mr. Augustine commented the FDA will begin inspecting compounding facilities and the Chapter 797 revision will be printed sometime in May or June and there will be a 90-day response time.

ADJOURNMENT

Zarek moved, seconded by Labenz, to adjourn the meeting at 3:40 p.m. Voting aye: Barr, Borchert, Labenz, and Zarek. Kaczmarek was absent. Voting nay: None. Motion carried.

Respectfully submitted,

(Signature on file with the Department)

Linda Labenz, Secretary
Board of Pharmacy